Open issues and next challenges in transcatheter mitral valve intervention

Valorisation of research

My own research over the last years has been focused on heart valve disease. In particular, the main focus was interventional mitral valve therapies. My interest in this regard was the direct consequence of the growing clinical importance of these new types of therapies, which have become progressively available to treat patients who were before denied to conventional surgical treatment, due to the high risk. This was mainly due to the rapid improvement of the technologies and of the imaging procedural guidance.

But the most challenging question are now, once several new devices are available and implantation has been demonstrated to be feasible: which patient really can profit from these new therapies? Which are the best candidates from an anatomical and clinical standpoint? Which is the best procedural timing in order to obtain a prognostic benefit?

I tried to answer to some of these questions with my research, which gave a significant contribution in this regard.

In particular, I started to focus on the MitraClip therapy that nowadays counts more than 40,000 implant worldwide. MitraClip therapy was initially proposed as an alternative to surgery, while now represent the ideal treatment for high risk or inoperable patients with both degenerative and functional mitral regurgitation, as recommended by the European and American Guidelines for the management of heart valve disease. However, there are still several open issues regarding patient selection and optimal timing.

I focused my research on both degenerative and functional disease in this regard.

In the next future, randomized trial should compare the outcome of surgery and MitraClip in high-risk elderly patients with degenerative MR in order to better define the optimal treatment for this population, which is growing according to the increase of life expectancy.

Regarding functional MR, MitraClip is progressively becoming the first line therapy, due to the fact that most of the patient presenting with this condition have prohibitive surgical risk. In order to obtain a prognostic benefit, MitraClip treatment should not be performed too late. Whether MitraClip can really confer survival benefit in heart failure patients with severe functional MR, has still to be demonstrated. This is the most important challenge of the next future, and the ongoing randomized COAPT trial (which compare optimal medical therapy to MitraClip in patients with severe functional MR) should definitely give an answer to this question.

The second part of my research presented in this text focuses on the Cardioband, which is a device to perform a complete percutaneous direct mitral annuloplasty, by implanting a surgical-like band on the atrial surface of the mitral annulus through a transseptal approach. The main advantages of the Cardioband are the high safety profile, due to the minimal impact on the physiology of the heart, and the fact that it keeps the door open for further interventional or surgical treatments. Our group was involved in the development of this technology from the real initial phase, since the concept was invented by Prof. Maisano. Cardioband obtained CE Mark in October 2015. Today,

about 100 high-risk patients have been treated. The next future challenges in this field are mainly three: 1) define the role of Cardioband as a combined therapy with other device (ie. MitraClip + Cardioband), 2) improve procedural Guidance with multimodality imaging, 3) define subgroup of patients with optimal results.

The last part of the manuscript describes other important aspect of modern mitral valve interventions: transcatheter mitral valve replacement and mitral paravalvular leak occlusion.

At the moment, one of the hottest topics in interventional cardiology is the future role of replacement versus repair technologies. Strongly believing that repair will remain the preferred approach and that the 2 methods will be complementary rather that competitive, in absence of data, we gave our contribution by defining some pathophysiologic and anatomical reasons to support why repair should be the preferred method. Since the experience with transcatheter replacement is at the moment really preliminary, any comparison is now just speculative. The next step will be to define the right therapy for the right patient, and this can be done only with rigorous randomized trials.

Finally, we focused on paravalvular leak occlusion. Traditionally, reoperative surgery to treat paravalvular leak has been associated with high risk of mortality. We were the first group to compare surgical results with transcatheter closure performed through transapical access. Transapical access is an alternative to the transseptal route, which has the advantage of a more direct approaching to the mitral valve. The long-term results of this relatively new approach have still to be defined, but our study was pioneering in this regards. Our results have to be confirmed on a larger bases in order to define the best candidate for transapical approach compared to the less invasive transseptal one.